REMARKS

Claims 1, 2, 4-17, 19, 20 and 22 are pending in this application and stand rejected. Reconsideration in view of the following remarks is respectfully requested.

Formal Matters

Applicants respectfully note that the formal matters raised in the present Office Action were addressed in the Applicant's response filed on 17 February 2010. Copending applications have been brought to the Examiner's attention, and all references disclosed in the specification have been properly submitted in an Information Disclosure Statement.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 22 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Briefly, the Examiner asserts that claim 22 is overly broad and includes the treatment of any disease or bacterial disease. Applicants traverse the rejection for reasons of record, as well as at least the following reasons.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991).

In the response filed 17 February 2010, claim 22 was amended to relate to a method for treating bacterial infections in humans and animals. Such a method obviously does not include the treatment of *any* disease. With regard to the treatment of bacterial infections generally, the specification provides data for the antibacterial activity for representative compounds of the invention against six different pathogens of different genera, including both Gram-positive and Gram-negative cocci. See, e.g., paragraphs [0285], [0608] and Table A, indicating that the compounds have broad spectrum antibacterial activity. Accordingly, the Applicant fails to see why claim 22 should be considered overly broad.

In view of the foregoing remarks, the Applicant respectfully submits that the specification provides sufficient guidance for a person or ordinary skill in the art to reasonably conclude that the inventor had possession of the invention as claimed, satisfying the written description requirement.

Accordingly, the Applicant respectfully requests the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Rejection Under 35 U.S.C. § 103

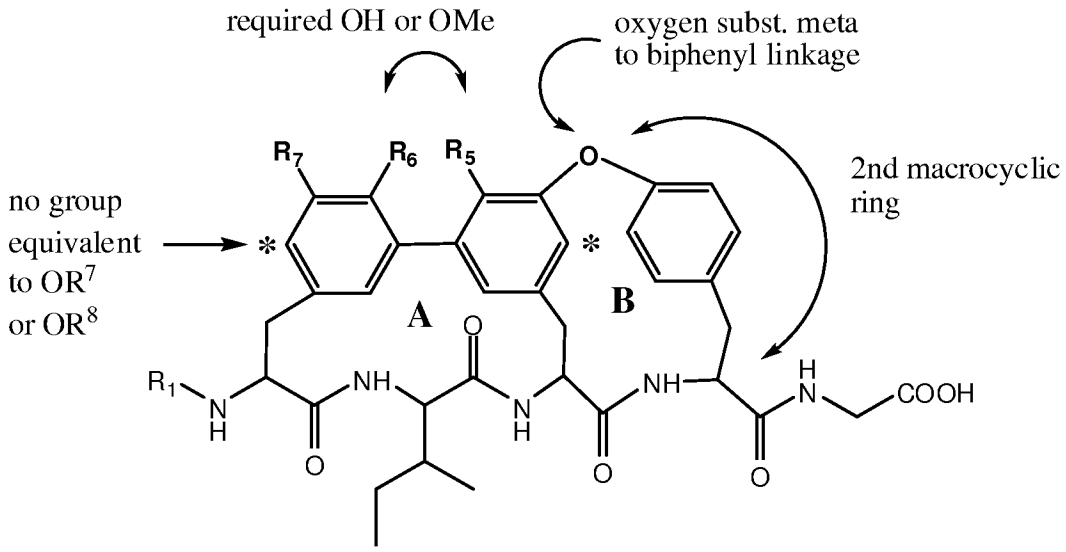
Claims 1, 2, 4-17, 19 and 22 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Clerc et al. (U.S. Patent 5,840,682) for reasons of record. Briefly, the Examiner takes the position that Clerc et al. discloses structurally similar antibacterial compounds which allegedly embrace the presently claimed invention. The Examiner asserts that the instant claims differ from the compounds of Clerc et al. in generic scope. The Applicants respectfully traverse the rejections for reasons of record, as well as at least the following reasons.

As the Federal Circuit recently reaffirmed in *Eisai v. Dr. Reddy's Laboratories Ltd.,* 87 USPQ.2d 1452 (Fed. Cir. 2008), in chemical compound cases, "[o]bviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. *Id.* at 1455 (citing *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007)).

The Examiner points to the Abstract and column 1, lines 21-22 of Clerc et al., wherein R is defined as NH-CH_2-COOH, and asserts the instant claims are obvious over Clerc's compounds of formula (I), when m, n and p are 0 and R is NH-CH_2-COOH. The Applicant respectfully but emphatically disagrees.

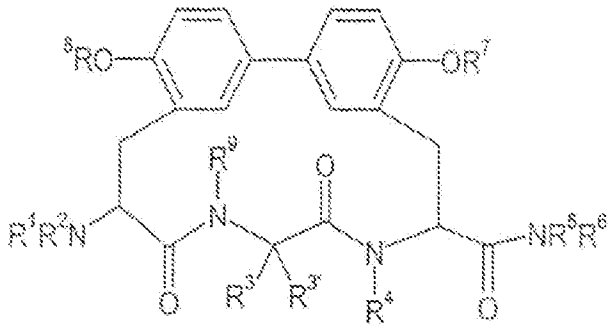
For ease of comparison, the compound of Clerc et al. proposed by the Examiner and the compound of formula (I) in instant claim 1 are shown below, highlighting the major structural differences between Clerc et al.'s compounds and the invention as claimed.

The proposed compound of Clerc et al. has the following structure:



As already noted by the Applicants, Clerc et al. discloses a bicyclic system, containing a second macrocyclic ring (labeled as Ring **B**, above) appended to the biphenyl-containing macrocyclic ring (labeled as Ring **A**, above) via a phenoxyphenyl linkage that links the biphenyl moiety to the position corresponding to $-NR^5R^6$ in the instant claims.

By comparison, the biphenomycin system of the present invention is a monocyclic system, having the structure of formula (I) as in claim 1, shown below. The Applicants submit that this difference alone is such that Clerc et al. cannot render the subject matter of the currently pending claims obvious.



(I),

In addition, the invention as claimed does not contain the required bis-hydroxy or bis-methoxy substituents at the positions labeled R_5 and R_6 in the compounds of Clerc et al., or the ethereal oxygen atom that forms part the second macrocyclic ring.

Moreover, the instant claims require additional oxygen-containing functionality at OR^7 and OR^8 at the positions para to the biphenyl ring linkage, while the corresponding positions in the compounds of Clerc et al. are unsubstituted.

Thus, there are at least three major structural differences between the compounds of the present invention and the compounds of Clerc et al. Therefore, even if one of skill in the art seeking to develop new pharmacologically active compounds started from the compounds of Clerc et al., the structural differences are such that the compounds of the present invention cannot be considered obvious over the compounds of Clerc et al.

As previously noted by the Applicants, Clerc et al. disclose that their compounds are antagonists of neurotensin, useful for the treatment of disorders associated with neurotensin. See e.g., col. 5, line 63 to col. 6, line. The Examiner has provided neither a motivation for the selection of the neurotensin antagonists of Clerc et al. as "leads" for the development of antibacterial agents, nor any basis why one of ordinary skill would have had a reasonable expectation that antibacterial agents would be successfully identified starting from such compounds.

Moreover, the Examiner has provided no rationale why one of skill in the art would have made the major structural modifications described in detail above that would be required to achieve the compounds of the present invention.

Accordingly, the Office has failed to establish a *prima facie* case of obviousness. The Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

Non-statutory obviousness-type double patenting rejection

Claims 1, 2, 4-17, 19 and 22 stand provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 1, 3, 26 and 27 of copending Application No. 11/453,375, now U.S. Patent No. 7,655,643.

Accompanying this response is a terminal disclaimer over U.S. Patent No. 7,655,643, obviating the grounds for rejection. Accordingly, the Applicants respectfully request that the non-statutory obviousness type double patenting rejection be withdrawn and the claims passed to issue.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 584212002400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: September 1, 2010

Respectfully submitted,

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